MEMORANDUM OF UNDERSTANDING

BETWEEN

THE NATIONAL INSTITUTE OF ALLERGY AND INFECTIOUS DISEASES,
NATIONAL INSTITUTES OF HEALTH,
DEPARTMENT OF HEALTH AND HUMAN SERVICES,
GOVERNMENT OF THE UNITED STATES OF AMERICA

and

THE WORLD HEALTH ORGANIZATION

This Memorandum of Understanding (MOU) is between the National Institute of Allergy and Infectious Diseases (NIAID), a component of the National Institutes of Health (NIH) within the United States Department of Health and Human Services (HHS), and the World Health Organization (WHO). NIAID and WHO are referred to hereinafter as "the Participants."

WHO has created the Health Emergencies Programme to improve global response to Public Health Emergencies of International Concern (PHEIC) and other health emergencies.

NIH participation in the initial assessment of disease outbreaks during public health emergencies is essential to inform the development and implementation of a research response.

To support WHO's efforts to improve the global response to PHEIC, the Participants intend to collaborate to promote faster and more effective research responses, particularly during public health emergencies caused by emerging and re-emerging infectious diseases. This collaboration may include planning for and conducting research through cooperative interaction before and during public health emergencies.

In addition to activities carried out in accordance with this MOU, the Participants intend to establish the NIAID-WHO Collaborating Center for Emerging Infectious Disease Response Research and Preparedness.

The Participants express their intent to collaborate in other areas related to their key competencies, including but not necessarily limited to activities listed below.

WHO activities with specific relevance to this collaboration include

- Developing policy advice through its various advisory and expert committees, and sharing this advice with Member States and other interested stakeholders
- Convening initial assessment and response teams in public health emergencies
- Facilitating national, regional and international regulatory agency collaboration to facilitate regulatory alignment and optimization, to provide scientific advice on the development of preventive, therapeutic and diagnostic countermeasures, and to accelerate regulatory input on and review of vaccine clinical trial applications and ethical reviews and approvals
- Identifying PHEIC as defined under the International Health Regulations (2005) and coordinating international response to contain and mitigate their impacts

NIAID activities with specific relevance to this collaboration include

- Providing scientific and technical expertise on the development of ethical research protocols, programmes, agendas, and research response frameworks for outbreaks in support of WHO's programs and activities, including WHO's Research and Development Blueprint for Actions to Prevent Epidemics and its Global Coordination Mechanism which brings together multiple research agencies, networks and funders to better coordinate and manage R&D and research response
- Providing qualified clinical and other research personnel with expertise in emerging infectious diseases to conduct early assessments of research response needs
- Training clinical research and technical support personnel
- Conducting or supporting and overseeing clinical trials and other targeted research in accordance with NIAID rules, regulations and practices, and in collaboration with the relevant WHO Member States' public health leadership and researchers
- Collecting and sharing clinical and laboratory data

Scope of the collaboration

The scope of collaborative activities under this MOU reflects a shared understanding by the Participants that research is an integral part of infectious disease emergency preparedness and response. In this regard, the Participants intend to:

- Improve coordination and communication between the Participants and partners related to research prior to and during infectious disease outbreaks
- Enable the rapid development and implementation of well-coordinated and targeted research agendas in response to specific outbreaks of emerging or re-emerging infectious disease
- Develop guidelines adapted to, and appropriate in, a specific emergency, while ensuring adherence to high-level ethical, scientific, and public health standards
- Work with partners and Member State governments to enhance research capacity, especially in developing countries
- Where consistent with each Participant's respective policies, invite the other Participant to take part in activities related to research concerning public health emergencies

1. Collaborative activities

Any collaborative activity as outlined above is subject to the availability of financial and human resources for that purpose, as well as each Participant's programme of work, priorities, internal rules, regulations, policies, administrative procedures and practices. The Participants intend that each collaborative activity be carried out on a case-by case-basis, subject to additional specific communications.

2. Funding

Each Participant is expected to be responsible for the funding of its activities under this MOU, except as may otherwise expressly be arranged in any subsequent communications.

Each Participant is expected to administer and handle its funds in accordance with its own financial regulations, rules, and administrative practices.

The Participants intend that any transfer of funds between them be made under an appropriate separate agreement, to be negotiated in good faith between them.

3. Confidentiality

It is acknowledged that each Participant may possess confidential information, which is proprietary to it or to third parties collaborating with it. The Participants intend that any such information only be shared

between the Participants under a separate mutually agreed upon confidentiality arrangement specifically covering such information.

4. Publications

Subject to each Participant's proprietary rights and/or the proprietary rights of others, including with respect to confidentiality, the results of any collaborative activity under this MOU may be published by researchers associated with either Participant. The Participants intend to encourage researchers associated with the Participants to: (a) publish the results of their joint work collaboratively; (b) follow guidelines relating to authorship of articles in major, international, peer-reviewed journals for purposes of designating authorship of collaborative publications; (c) to avoid prejudicing proprietary rights and the confidentiality of information, transmit to the Participants for their review any results of any collaborative activity under this MOU intended to be published, at least 30 days before a proposed publication is submitted to any editor, publisher, referee or meeting organizer; and (d) acknowledge both Participants in any publication of results of any collaborative activity under this MOU, and give each Participant an opportunity to review such acknowledgment and request reasonable changes to the use of its name, or that its name be deleted altogether.

5. Use of the Participants' names

Except as explicitly provided in this MOU, the Participants intend that neither Participant, in any statement or material of a promotional nature, refer to the relationship of the other Participant to the collaboration pursuant to this MOU, or otherwise use the other Participant's name, acronym and/or emblem, without the prior written consent of the other Participant.

6. Duration

The MOU may commence from the date of last signature and remain in effect for a period of five years. This MOU may be discontinued by either Participant, subject to six months' advance written notice to the other Participant. In the event of discontinuation of this MOU, the operation and duration of ongoing projects are not intended to be affected, unless the Participants mutually consent otherwise.

6. Non- binding Intent

This MOU does not create legally binding obligations under international law, the law of the United States, or the law of Switzerland.

7. Modifications

This MOU may be modified in writing by mutual consent of the Participants.

8. Privileges and Immunities of WHO

Nothing contained herein is construed as a waiver of any of the privileges and immunities enjoyed by WHO under national or international law, such as immunity from national court jurisdiction.

9. Focal Points

Each participant intends to nominate a focal point to facilitate coordination between NIAID and WHO in respect of any matters arising from this MOU.

10. Steering Group

A Steering Group made up of representatives of WHO and NIAID, may be established to guide collaboration under this MOU and confer on a regular basis to develop mutually agreed work plans, to evaluate progress, and to make recommendations, as appropriate.

Signed, in duplicate, in the English language on April 20, 2018, in Bethesda, Maryland, United States.

For the World Health Organization

Tedros Adhanom Ghebreyesus, Ph.D., M.Sc.
Director-General, WHO

For the National Institute of Allergy and Infectious Diseases, U.S. National Institutes of Health, HHS

Anthony S. Fauci, M.D.
Director, NIAID